

WHAT IS CLAIMED IS:

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1. A method of producing a container comprising the steps of:

forming a container in a forming device,

transferring said container to an environmentally controlled area to maintain a predetermined cleanliness level, and

cleaning said container.

2. The method of claim 1, further comprising:

enclosing said container in a second container, and
sterilizing said container.

3. The method of claim 1, wherein said container is formed from glass and said method comprises forming said container in a glass forming device and heating said container to an annealing temperature to simultaneously anneal and clean said container to form said container.

4. The method of claim 1, further comprising filling said container with a desired substance and coupling a closure member to said container to close said container.

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5. The method of claim 1, comprising enclosing said forming device in a locally controlled area to maintain a predetermined cleanliness level.

6. The method of claim 1, wherein said container is a syringe barrel and said syringe barrel is formed from glass or plastic.

7. The method of claim 6, comprising the steps of applying a tip cap to close a first end of said syringe barrel, filling said syringe barrel with a substance, applying a stopper to a second end of said syringe barrel to form a prefilled syringe.

8. The method of claim 6, further comprising the step of directing a stream of filtered air to said syringe barrel in said environmentally controlled area to remove particulates from surfaces thereof to clean said syringe barrel.

9. The method of claim 8, wherein said stream of air comprises ionized air.

10. The method of claim 1, wherein said container is a glass syringe barrel and said method comprises forming said syringe barrel by heating a glass tube to a temperature of about 760°C to 1100°C.

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11. The method of claim 10, further comprising annealing said syringe barrel at a temperature of at least about 560°C.

12. The method of claim 1, wherein said environmentally controlled area maintains a cleanliness level of about Class 100.

13. The method of claim 1, wherein said environmentally controlled area comprises at least one housing assembly having an air blower and a HEPA filter coupled to said air blower to filter air entering said at least one housing assembly.

14. The method of claim 13, wherein said at least one housing assembly is maintained at a positive internal pressure to prevent unfiltered air from entering said housing assemblies.

15. The method of claim 6, further comprising applying a coating of a lubricant to an inner surface of said syringe barrel.

16. The method of claim 10, wherein said forming step comprises heating a first end of a glass tube to a temperature whereby said glass tube is pliable and shaping said first end to form a flange extending substantially radially outward from a center axis of said glass tube.

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17. The method of claim 16, further comprising heating a second end of said glass tube to a temperature whereby said glass tube is in a pliable state and shaping said second end for receiving a cannula needle.

18. The method of claim 1, further comprising filling said container with a substance.

19. A method of producing prefillable glass syringe barrel assemblies comprising the steps of:

forming a plurality of clean syringe barrels in a glass forming device for shaping a cylindrical glass tube into syringe barrels having a first open end for receiving a syringe plunger and a second open end for discharging contents from said syringe barrels;

annealing said glass syringe barrels at a temperature of at least 500°C; and

immediately transferring said syringe barrels to at least one housing assembly for maintaining a predetermined cleanliness level.

20. The method of claim 19, further comprising coupling at least one syringe component to said syringe barrels to form a plurality of syringe barrel assemblies, forming an array of syringe barrel assemblies in said at

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least one housing assembly, placing said array in a container and closing said container to form said syringe barrel assemblies.

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21. The method of claim 20, wherein said forming step comprises supplying a cylindrical glass tube to said forming device and heating a first end of said glass tube to a temperature whereby said glass tube is pliable and forming a flange about said first open end and heating a second end of said glass tube to a temperature whereby said glass tube is pliable and forming a tip at said second end.

22. The method of claim 21, wherein said first and second ends of said glass tube are heated to a temperature of about 760°C to 1100°C.

23. The method of claim 21, further comprising annealing said syringe barrels by heating to at least about 560°C.

24. The method of claim 20, further comprising the step of cleaning said syringe barrels in said at least one housing assembly prior to forming said array.

25. The method of claim 24, wherein said cleaning step comprises directing a stream of filtered, ionized air onto said syringe barrels to remove particulates from surfaces thereof.

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26. The method of claim 20, wherein said at least one housing assembly includes an air blower and a HEPA filter coupled to said air blower to filter air entering said housing assembly and maintain a cleanliness level of about Class 100.

27. The method of claim 19, wherein said at least one housing assembly is maintained at a positive internal pressure to prevent unfiltered air from entering said housing assembly.

28. The method of claim 20, further comprising transferring said syringe barrels to a second housing assembly and applying a coating of a lubricant to an inner surface of said syringe barrels prior to forming said array.

29. The method of claim 28, further comprising transferring said syringe barrels to a third housing assembly and packaging said syringe barrels while in said third housing assembly.

30. The method of claim 19, wherein said forming device is enclosed in a housing assembly for maintaining a predetermined cleanliness level.

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31. The method of claim 30, wherein said housing assembly enclosing said forming device maintains a cleanliness level of about Class 100.

32. The method of claim 19, wherein said syringe barrels are immediately transferred to said at least one housing assembly after forming to maintain a predetermined cleanliness standard.

33. A method of producing a filled syringe comprising the steps of:

forming a plastic syringe barrel in an injection molding machine, said syringe barrel having a cylindrical side wall, an open proximal receiving end and a frustoconically shaped outlet nozzle at its distal end;

transferring said syringe barrel, without any additional cleaning or sterilization, into an environmentally controlled area to maintain a predetermined cleanliness level;

directing a stream of filtered air toward said syringe barrel in said environmentally controlled area to remove particles from surfaces thereof to clean said syringe barrel;

delivering a tip cap to said environmentally controlled area;

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air cleaning said tip cap in said environmentally controlled area;

assembling said tip cap to said outlet nozzle of said syringe barrel to close said outlet nozzle;

filling said syringe barrel with a substance through its open proximal end;

delivering a stopper to said environmentally controlled area;

inserting said stopper into said open proximal end of said barrel to form a prefilled syringe; and

removing said prefilled syringe from said environmentally controlled area.

34. The method of claim 33, further including the step of packaging said prefilled syringe.

35. The method of claim 33, further including the step of sterilizing said prefilled syringe.

36. The method of claim 33, further including the steps of sterilizing said prefilled syringe followed by the step of packaging said prefilled syringe.

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37. A method of producing a filled syringe comprising the steps of:

forming a plastic syringe barrel in an injection molding machine, said syringe barrel having a cylindrical side wall, an open proximal receiving end and a frustoconically shaped outlet nozzle at its distal end;

transferring said syringe barrel, without any additional cleaning or sterilization, into an environmentally controlled area to maintain a predetermined cleanliness level;

directing a stream of filtered air toward said syringe barrel in said environmentally controlled area to remove particles from surfaces thereof to clean said syringe barrel;

delivering a stopper in said environmentally controlled area;

inserting said stopper into said open proximal end of said syringe barrel to close said proximal end;

filling said syringe barrel with a substance through its outlet nozzle;

delivering a tip cap to said environmentally controlled area;

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air cleaning said tip cap in said environmentally controlled area;

assembling said tip cap to said outlet nozzle of said syringe barrel to form a prefilled syringe; and

removing said prefilled syringe from said environmentally controlled area.

38. The method of claims 37, further including the step of packaging said prefilled syringe.

39. The method of claims 37, further including the step of sterilizing said prefilled syringe.

40. The method of claims 37, further including the steps of sterilizing said prefilled syringe followed by the step of packaging said prefilled syringe.

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New Abstract